IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, v. GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma, and the OKLAHOMA INSURANCE DEPARTMENT, Defendants.	)	Civil Action No. CIV-19-977-J

PLAINTIFF PCMA'S REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Defendants' arguments ignore the will of Congress and downplay the impact of the Patient's Right to Pharmacy Choice Act (the "Act"). While the express preemption standards in ERISA and Medicare Part D are not co-extensive, in both statutes Congress sought to prevent states from adopting laws that promote local interests at the expense of national objectives. Here, the Act does exactly that. The Act protects the interests of local independent pharmacists to the detriment of health plans' ability to effectively determine and provide benefits to plan beneficiaries. PCMA is entitled to judgment as a matter of

law, and the Court should grant its Motion.[1]

In this reply brief, PCMA addresses five specific arguments in Defendants' Opposition:[2] (1) that ERISA's express preemption standard is akin to a conflict preemption standard; (2) that the Act only indirectly affects ERISA plans; (3) that the Act is a cost regulation; (4) that the Act is saved from ERISA preemption by the Insurance Savings Clause; and (5) that Medicare Part D preemption requires a specific "overlap" between federal and state law. Dkt. 100. Each of these arguments is meritless; PCMA addresses each in turn.

I. ERISA preempts all state laws in the area of ERISA regulation, not just those in conflict with federal law.

Defendants suggest that ERISA's express preemption provision only preempts those state laws that "run counter" to ERISA's standards. Dkt. 100 at 9. This is false. Nothing in the statute indicates that Congress intended to limit ERISA preemption to a conflict standard. Nor does the decisional law support such a cramped view. *See, e.g.*, *Egelhoff v. Egelhoff*, 532 U.S. 141, 146, (2001) ("We have observed repeatedly that [ERISA's] broadly worded [express preemption] provision is 'clearly expansive.'"). For

[1] Defendants' Opposition does not dispute any material facts in Plaintiff's Motion, nor do they offer any other facts that are material and disputed. As there is no dispute of material facts, the case is ripe for summary judgment.

[2] This Reply only offers arguments on points raised in Defendants' Opposition (Dkt. 100) that were not previously addressed in Plaintiff's Memorandum in Support of Summary Judgment (Dkt. 97-1). Local Rule 7.1(i). While some of the authorities in this Reply were also cited in the Plaintiff's opening brief, these authorities are only cited to address new arguments raised in Defendants' Opposition.

example in *Gobeille*, the Vermont law at issue did not conflict with ERISA provisions yet was preempted because it regulated conduct in one of the same general areas that ERISA regulated, i.e., plan reporting and disclosure requirements. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 945 (2016). The Court recognized that ERISA reserves for the federal government *all* regulation of ERISA plans *within the areas generally addressed by ERISA* even where there are no federal standards on a specific topic. *Id.* (noting the Secretary of Labor "*may be* authorized to require ERISA plans to report data similar to that which Vermont seeks") (emphasis added). Here, the Act is preempted because it regulates areas of core ERISA concern including plan design and central administrative matters. *See* Dkt. 97-1 at 15-21.

II. The Act directly affects ERISA plans beyond the merely economic.

Speculating that some ERISA plans may manage their own pharmacy benefits rather than engage a PBM, Defendants assert that the Act only causes an indirect economic impact on plans and therefore avoids ERISA preemption. This argument is legally irrelevant and ignores the undisputed practical effects of the Act on ERISA plans.

First, whether plans could theoretically avoid compliance with the Act by performing pharmacy benefits management in house is of no legal significance for purposes of ERISA preemption.[3] Dkt. 100 at 4. In *Gobeille v. Liberty Mut. Ins. Co.*, for

[3] Moreover, the Act applies to ERISA plans regardless of whether they engage an outside PBM to manage their pharmacy benefits. The Act defines a PBM as "a person that performs pharmacy benefits management" for a "managed-care company," "insurance company," "third party payor," or other enumerated entities that offer health plans. 36

example, Liberty Mutual could have avoided compliance with the Vermont reporting and disclosure requirements by choosing not to engage a third-party administrator. *See generally* 136 S. Ct. 936 (2016). Liberty Mutual's choice to hire a third-party administrator was surely one of "staffing and resources," but this choice played no role in the Court's analysis. Instead, the Court focused on the nature of the regulation on areas of core ERISA protection to hold that the law was preempted by ERISA. *Id*. *De Buono* is also consistent with this conclusion. There, New York State imposed a tax on all hospitals, including three medical centers owned and operated by an ERISA plan for its members. *See De Buono v. Nysa-Ila Med. & Clinical Servs. Fund*, 520 U.S. 806 (1997). The Court concluded that the hospital tax was a law of "general applicability" affecting the cost of benefits and not a law "[requiring] employers to provide certain benefits." *Id.* at 815-16. Again, whether the particular employee benefit plan outsourced health care services to other providers or provided them in-house did not affect the Court's reasoning. *Id.*; *see also Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 480 (2020) (attaching no legal significance for purposes of preemption to whether the regulated activity was being performed by the plan itself or outsourced to a third party). The same is true here. The Act is preempted because it dictates plan benefit design and regulates other areas of core ERISA concern regardless of whether a plan could theoretically manage its own pharmacy benefits.

O.S. §6960(3). This definition does not distinguish between pharmacy benefits management performed by the plan itself and those outsourced to a third-party PBM.

Second, "for most if not all" ERISA plans, managing a pharmacy benefits plan without a PBM "is a practical impossibility." *Pharm. Care Mgmt. Ass'n v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010); *see also* Dkt. 97-1 Exhibit 3 (Pl. Ex. 3), ¶ 32; Pl. Ex. 5, ¶ 32. A state law is "subject to [ERISA] pre-emption if 'acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage.'" *Rutledge*, 141 S. Ct. at 480 (quoting *Gobeille*, 136 S. Ct. at 943). In contrast to Defendants' assertions, Dkt. 100 at 5, the practical impossibility for plans of managing their own pharmacy benefits, does not leave them "free to choose whether to hire a PBM." Here, the costs of "forgoing the economies of scale, purchasing leverage, and network of pharmacies only a PBM can offer" are so high that "most if not all" plans will be forced to adopt Oklahoma's preferred benefit design. *See Pharm. Care Mgmt. Ass'n*, 613 F.3d at 188. For this reason, the Act is preempted.

III. The Act restricts benefit design in a manner distinct from cost regulation.

Defendants mistakenly conclude that the Act affects ERISA plans in a manner that is similar to the Arkansas PBM Law ("Act 900") at issue in *Rutledge v. PCMA*. Dkt. 100 at 6. Defendants, however, overlook how Act 900's features and intended impacts fundamentally differ from those in the Act. They also overlook the significance that such distinctions have on the ERISA preemption analysis. *See generally, Rutledge*, 141 S. Ct. at 480. The Court held that Act 900 was permissible because it was a mere cost regulation, whereas here, the Act relates to plans' capacities to design and structure plan benefits, areas that are quintessentially within ERISA's preemptive scope. *Id*; *see also*

New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995); *compare Gobeille*, 136 S. Ct. 936. Act 900 "establishe[d] a floor for the cost of the benefits that plans choose to provide." *Rutledge*, 141 S. Ct. at 482. The Court rejected the argument that "mandating a particular pricing methodology" regulated plan design because a mandatory price floor did "not require plans to provide any particular benefit to any particular beneficiary in any particular way." *Id*. Here, in contrast, the Act requires plans to provide benefits under specific conditions, prohibiting plans from controlling access to benefits at particular pharmacies, under particular cost-sharing terms. *See* Dkt. 97-1 at 15-20.

Defendants' assertion that the Act is merely a "modest" anti-steering provision also ignores the manner in which the Act regulates plans. Dkt. 100 at 6. As Justice Thomas, writing for a unanimous court in *Dillingham*, makes clear: state laws in areas of traditional state regulation are not "immun[e]" from ERISA preemption.[4] *Cal. Div. of Lab. Standards Enf't v. Dillingham Const., N.A., Inc.*, 519 U.S. 316, 329 (1997) ("ERISA certainly contemplated the pre-emption of substantial areas of traditional state regulation."). Here, the Act is not a law of general applicability, but one targeted to

[4] Defendants misleadingly quote *Dillingham* to support their assertion that "anti-steering laws are 'a hazard with which ERISA is not concerned,'" Dkt. 100 at 5. *Dillingham* involved a California prevailing wage law, not an anti-steering law, and the language Defendants quote is unrelated to anti-steering laws but instead clarifies that ERISA only applies to benefits paid from a separately accumulated benefit fund and not expenses from an employer's general assets. 519 U.S. at 327 (stating "[b]enefits paid out of an employer's general assets" as opposed to those paid out of a separately accumulated fund is "a hazard with which ERISA is unconcerned").

employee benefit plans by prohibiting a panoply of commonly used plan designs. Dkt. 97-1, 17-18.

Defendants are unable to point to a single case in which a court has found a state law that dictates the terms under which a beneficiary may access their benefits did not "relate to" ERISA plans. Instead, the Supreme Court has consistently held that state laws, like the Act, which dictate the terms on which a beneficiary can access their benefits, are preempted by ERISA. *See Shaw v. Delta Air Lines*, 463 U.S. 85, 108-09 (1983); *see also Egelhoff v. Egelhoff*, 532 U.S. 141, 152 (2001). *Travelers* is entirely consistent with this principle. There, unlike *Shaw* or *Egelhoff*, the law at issue merely regulated the "costs of benefits" and the "relative attractiveness" of certain providers to the plan. *See New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 660 (1995). It did not restrict a plan's ability to incent or restrict the beneficiary's choice of providers. *Id.*

IV. The Act is not saved by the Savings Clause.

Defendants' argument regarding the Supreme Court's holding in *Kentucky Ass'n of Health Plans* is unpersuasive for three reasons: (1) Defendants misunderstand the analysis for Insurance Savings Clause; (2) the Act is not a law regulating insurance; and (3) even if provisions are saved, the Deemer Clause would still preempt that Act as to self-insured plans.

Defendants assert that the Court in *Kentucky Ass'n of Health Plans* did not find a Kentucky Any Willing Provider law had a "connection with" ERISA plans. Dkt. 100 at 7. This is incorrect and mischaracterizes the framework for Insurance Savings Clause

analysis. The Insurance Savings Clause carves out an exception from ERISA's express preemption provision for state laws that regulate insurance. 29 U.S.C. §1144(b) (the "Insurance Savings Clause"). In order to conclude that a state law is saved from preemption by the Insurance Savings Clause, a court must first conclude the state law would otherwise be preempted. *Nat'l Elevator Indus., Inc. v. Calhoon*, 957 F.2d 1555, 1557 (10th Cir. 1992) (stating that a law "relates to" ERISA is a requirement before assessing whether the "exception" of § 1114(b) applies); *Ky. Ass'n of Health Plans, Inc. v. Nichols*, 227 F.3d 352, 357 (6th Cir. 2000) (stating court "must" determine if the law is preempted, and then decide whether is it saved). The Kentucky Any Willing Provider law's impermissible connection with ERISA plans was therefore a predicate to the Court's holding that the law was saved by the Insurance Savings Clause. *See Ky. Ass'n of Health Plans v. Miller*, 538 U.S. 329, 333, 342 (2003).

In any event, the Act here is not saved.[5] Whether a state law "regulate[s] insurance" depends upon two factors: (1) the state law "must be specifically directed toward entities engaged in insurance" and (2) the state law must "substantially affect the risk pooling arrangement between the insurer and the insured." *Ky. Ass'n of Health Plans v. Miller*, 538 U.S. 329, 342 (2003). Here, the Act does not affect the risk pooling arrangement between the insurer and the insured. Unlike *Ky. Ass'n of Health Plan*, the

[5] Defendants' argument relating to the Insurance Savings Clause was raised for the first time in their opposition motion, and relegated to a single footnote. As such, Defendants waived any argument regarding the Insurance Savings Clause by not properly raising the issue. *See, e.g., United States v. Ellis*, 868 F.3d 1155, 1181 (10th Cir. 2017) ("Arguments raised in a perfunctory manner, such as in a footnote, are waived.").

Act does not "expand[] the number of providers from whom an insured may receive health services." *Id.* at 338. Instead, the Act targets preferred pharmacy networks and essentially requires their overlap with non-preferred networks. This doesn't change the number of pharmacies in-network for beneficiaries; just the terms under which beneficiaries can access those pharmacies.

Moreover, state laws that are saved from preemption by the Insurance Savings Clause are not enforceable as to self-insured plans. 29 U.S.C. §1144(b)(2) (no self-insured plan "shall be deemed to be an insurance company or other insurer… or to be engaged in the business of insurance" for purposes of any state law regulating insurance) (the "Deemer Clause"); *Ky. Ass'n of Health Plans v. Miller*, 538 U.S. 329, 336 n.1 (2003) (the Deemer Clause affects "state laws saved from pre-emption by [the Insurance Savings Clause] that would, in the absence of [the Deemer Clause] be allowed to regulate self-insured employee benefit plans"). Therefore, even if certain provisions of the Act are saved by the Insurance Savings Clause, the Act remains preempted as to self-insured plans.

V. Congress sought to maintain exclusive federal oversight of the Medicare Part D Program

Defendants' narrow construction of the Medicare Part D preemption standard interferes with Congress and CMS's ability to manage this fully funded federal benefit program. Defendants' "overlap" standard requires Congress and CMS to speak affirmatively and specifically to any potential state requirement to warrant preemption. Dkt. 100 at 12 ("we cannot infer from silence that something was 'deliberately left

open'"). This narrow reading of the Part D preemption provision conflicts with Congress's choice to adopt "a market-based model" for the Part D benefit. 70 Fed. Reg. 4194, 4244. By design, Congress left certain aspects of the prescription drug benefits to the Part D sponsors. *See* 42 U.S.C. §1395w-111(i) (the Non-Interference Clause). Defendants' overlap standard would make it overly burdensome for Congress and CMS to benefit from market-based competition and deliberately leave aspects of Part D plan design to the discretion of Part D plan sponsors without the potential for state interference. *See Pharm. Care. Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018) (Medicare Part D preempts state law permitting pharmacies to decline to dispense a prescription paid below costs where Medicare regulations are silent on that issue).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 8, 2021, I electronically transmitted the attached document to the Clerk of the Court using the Electronic Case Filing System for filing. Based on the records currently on file in this case, the Clerk will transmit a Notice of Electronic Filing to those registered participants of the ECF System.

/s/ Andrew M. London